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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/635,054	08/06/2003	Chester A. Metcalf III	411F US	1341

7590 02/17/2005

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EXAMINER	
KIFLE, BRUCK	
ART UNIT	**PAPER NUMBER**
1624	

DATE MAILED: 02/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/635,054	METCALF ET AL.	
	Examiner	Art Unit	
	Bruck Kifle, Ph.D.	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 August 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39* is/are pending in the application.

4a) Of the above claim(s) *33 and 35-39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-32 and 34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *09/16/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-32 and 34, drawn to compounds, compositions and methods of use of the same, classified in class 540, subclass 456.

II. Claims 33 and 35-37, drawn to methods of treating various diseases with combination therapy, classified in class 514, various subclasses depending on the nature of the additional compounds used.

III. Claims 38 and 39, drawn to a drug eluting stent, classified in class 623.

The inventions are distinct, each from the other because of the following reasons:

Groups I-III are drawn to patentably distinct and independent inventions. Group II is drawn to methods using complex pharmaceutical compositions which raise different issues of patentability and require search of each additional ingredient resulting in a multitude of searches, which is burdensome to the office. Group III is drawn to a stent which is patentably distinct and independent from group I.

Note that compounds, corresponding compositions, a method of use and a process of making that are of the same scope are considered to form a single inventive concept. The instant claims are not so linked as to form a single inventive concept.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and because the search required for Group I is not required for Group II or III, restriction for examination purposes as indicated is proper.

During a telephone conversation with Mr. David Berstein on February 16, 2005 a provisional election was made with traverse to prosecute the invention of group I, claims 1-32 and 34. Affirmation of this election must be made by applicant in replying to this Office action. Claims 33 and 35-39 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

Claims 1-32 and 34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

i) The phrase following the structural formula reads "and pharmaceutically acceptable derivatives thereof." This is indefinite because one skilled in the art cannot say what constitutes a pharmaceutically acceptable derivative and what does not. The metes and bounds of a derivative is undeterminable. Do Applicants intend a pharmaceutically acceptable salt or is more intended? Also, the claim language should read "or a pharmaceutically acceptable salt thereof" to be of proper Markush form.

ii) In the definition of Q, V is defined as "an aliphatic, heteroaliphatic, aryl, or heteroaryl moiety." The term "heteroaryl" is indefinite because it is not known how many atoms are

present, how many and what kind of heteroatoms are involved, what size ring is intended and how many rings are present. The term "heteroaliphatic" is indefinite because it is not known how many atoms are present, which atoms are present and where a ring is present, what kind of a ring (monocyclic, bicyclic, spiro, fused, bridged, saturated, etc.) is intended. Similarly, in "aliphatic" one cannot say what these groups look like (see also R^2 and R^5).

iii) When two R^2, R^5 and/or R^6 are chemically linked to form a ring, it is not known what size ring is formed, which atoms are present, what the degree of saturation is and how many rings are present.

iv) In the definition of "M", a group M-M' is present. The group M' is not defined and it is unclear what moiety M-M' is which may or may not be saturated. In the definition of $(M)_x$ one can only envision an alkylene linker. The group M' and M-M' are unclear.

v) The term "substituted" without saying which substituents are intended is indefinite. One skilled in the art cannot say which substituents are permitted and which ones are not.

vi) The group "acyl" is unclear. Is only alkanoyl intended or is more intended. Are the groups aroyl and heteroaroyl embraced by this group or not. A clarification is required.

vii) The provisos in the claims include groups that are not claimed to begin with. See for example in claim 1, "immunogenic carrier material, detector carrier material or a solid matrix." Such groups are not claimed but are excluded. Appropriate correction is required. Also, in "W" the group "U" cannot be O, S, SO or SO_2 and the ring nitrogen is missing an attachment resulting in a dangling valency. Correction is required. The group substituted or unsubstituted amino group is also unclear.

viii) In claim 22, the phrase "compound comprising a derivative of rapamycin or 43-epi-rapamycin" is indefinite because the metes and bounds of the derivatives cannot be ascertained. Also a compound cannot comprise something else. Correction is required.

ix) The pharmaceutically acceptable vehicle" in claims 27-32 and 34 is unclear.

Claim 34 is drawn to the treatment of cancer. The specification does not provide enablement for the treatment of cancer generally. No compound has ever been found that can treat cancers generally even though massive efforts have been directed towards this end. Since this assertion is contrary to what is known in oncology, proof must be provided that this revolutionary assertion has merits. Nearly all-anticancer drugs are effective against only a limited group of related cancers. Therefore, a compound effective against cancer generally would be a revolutionary exception. Applicant is asserting that he succeeded where others have failed. Where extensive efforts have all failed, it is reasonable for the Patent and Trademark Office to require proof that the claimed invention actually works for this specific utility. It is well established that a utility rejection is proper when scope of enablement is not reasonably correlated to the scope of the claims. (In re Vaeck 20 USPQ2d 1439, 1444, In re Ferens 163 USPQ 609).

In re Buting 163 USPQ 689 establishes that even clinical tests showing that a compound found to be useful in the treatment of two types of cancers was not sufficient for a much broader range.

If the provisos are present to exclude prior art, Applicants are urgently requested to point to these compounds in the prior art because the disclosure of the excluded compounds is material to the examination of this case.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Skotnicki et al. (US 5,391,730). The claims read on the compound of example 2 which has the group -O-C(O)NH(P=O)$(OEt)_2$ corresponding to instant J-Q-A-.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-32 and 34 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-32 and 34 of copending Application No. 10/357,152. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claims 1-32 and 34 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-32 and 34 of copending Application No. 10/862,149. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruck Kifle, Ph.D. whose telephone number is 571-272-0668. The examiner can normally be reached Tuesdays to Fridays between 8:30 AM and 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund J. Shah can be reached on 571-272-0674. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bruck Kifle, Ph.D.
Primary Examiner
Art Unit 1624

BK
February 16, 2005